

## **6000 Division of Substance Abuse and Mental Health**

### **6001 Substance Abuse Facility Licensing Standards**

#### **1.0 Purpose**

The Department is issuing these regulations to promote the health and well being of consumers/clients receiving services in substance abuse treatment facilities located within the State of Delaware. They are not intended to limit additional contract standards for substance abuse treatment facilities and programs with which a service provider may be expected to comply.

#### **2.0 Authority and Applicability**

The Department is authorized by 16 **Del.C.**, Ch. 22 to license and regulate substance abuse treatment facilities. These regulations shall apply to any facility as defined in 16 **Del.C.**, Ch. 22, and address the minimum acceptable standards and programmatic conditions for consumers/clients receiving services in substance abuse treatment facilities. No organization or entity shall manage or operate a substance abuse treatment facility within the State of Delaware unless it has been so licensed by the Department.

#### **3.0 Definitions**

The following words and terms, when used in these regulations, shall have the following meaning unless the context clearly indicates otherwise:

**“Adjunct and alternative therapy”** means a specific modality of therapy based on a specific valid body of knowledge, provision of which requires specific credentials. Examples include, but are not limited to, Psychodrama; Art Therapy; Music Therapy; Acupuncture; Massage Therapy; EMDR; etc.

**“Administrator”** means an individual who is authorized by the governing body to provide overall management of the agency.

**“Admission”** means the point in a client’s relationship with a program when the intake process has been completed and the program begins to provide additional services.

**“Advisory Council”** means a group of individuals approved by the governing body, to provide community input and recommendations to the governing body.

**“Agency”** means any partnership, corporation, association, or legal entity except for an individual practitioner, that provides, is seeking to provide, or holds itself out as providing alcohol and/or other drug treatment or rehabilitation services. An agency may operate more than one program.

**“Applicant”** means any agency that has submitted a written application for a license to operate an alcohol and/or other drug abuse treatment or rehabilitation program in Delaware.

**“Client”** means an individual who receives, or has received services from an agency.

**“Client Record”** means the official legal written file for each client containing all the information required by these regulations, and maintained to demonstrate compliance with these regulations.

**“Clinical Director”** means an individual who, by virtue of education, training, and experience, satisfies the requirements of 6.1.2.1 of these regulations and is authorized by the Administrator and/or the governing body to provide clinical oversight of the treatment program. The Clinical Director may also serve as Clinical Supervisor when directed to do so by the agency’s governing body.

**“Clinical Supervisor”** means an individual who, by virtue of education, training, and experience, satisfies the requirements of 6.1.3.1 of these regulations; and is authorized by the Administrator and/or the governing body to provide clinical supervision for all clinical staff.

**“Continuing care”** means those services recommended to the client upon discharge from a program that support and increase the gains made during the client’s treatment at that program.

**“Counseling”** means the process in which a Counselor I or Counselor II works with a client, family, significant other, or a group of clients, families or significant others, to assist them to understand issues, consider alternatives, and change behaviors.

- Individual counseling is the face-to-face interaction between a Counselor I or Counselor II and an individual client for a specific therapeutic purpose.
- Family counseling is the face-to-face interaction between a Counselor I or Counselor II and the family member(s)/significant other(s) of a client for a specific therapeutic purpose.
- Group counseling is the face-to-face interaction between a Counselor I or Counselor II and two or more clients or clients’ families/significant others for a specific therapeutic purpose.

**“Counselor I”** means an individual who, by virtue of education, training, and experience meets the requirements of 6.1.4.1 of these regulations and functions under the supervision of a Clinical Supervisor.

**“Counselor II”** means an individual who, by virtue of education, training and experience, meets the requirements of 6.1.5.1 of these standards and functions under the supervision of a Clinical Supervisor.

**“Cultural Competence”** means acceptance and respect for difference, continuing self-assessment regarding culture, careful attention to the dynamics of difference, continuous expansion of cultural knowledge and resources, and a variety of adaptations to service models in order to better meet the needs of minority populations. Culturally competent agencies work to hire unbiased employees, seek advice and consultation from the minority community, and actively decide what they are and are not capable of providing to minority clients. (March, 1989, Towards a Culturally Competent System of Care, Volume 1, National Technical Assistance Center for Children’s Mental Health, Georgetown University Child Development Center, p. 17.)

**“Day”** unless otherwise specified, one (1) day is a calendar day.

**“Deemed status”** means a licensure standing approved by DSAMH and bestowed upon programs that have been accredited by an accreditation body approved by DSAMH. Programs that have been granted Deemed Status will be inspected in accordance with Section 4.3.2 of these standards.

**“Designee”** means the person who is delegated tasks, duties, and responsibilities when such designation is permitted by these regulations.

**“Discharge”** means the point at which a client’s active involvement with an agency is terminated.

**“Division/DSAMH”** means the Delaware Division of Substance Abuse and Mental Health within the Delaware Department of Health and Social Services.

**“Division Director”** means the Director of the Delaware Division of Substance Abuse and Mental Health within the Delaware Department of Health and Social Services, or his/her designee.

**“Documentation”** means a written record acceptable as evidence to substantiate compliance with these regulations.

**“DSM”** means the Diagnostic and Statistical Manual of Mental Disorders, most recent edition, as published by the American Psychiatric Association.

**“Facility”** means the physical area, grounds, building(s) or portions thereof, under direct program administrative control.

**“Follow-up”** means the process for determining the status of an individual who has been referred to an outside resource for services or who has been discharged from services OR the process for determining an agency’s compliance with these standards after an agency audit has been completed.

**“Governing Body”** means the individual or individuals responsible for the overall management of an agency, responsible for ensuring compliance with 5.0 of these regulations.

**"Initial Treatment Plan"** means a preliminary plan that addresses the short term goals the program plans to achieve in the earliest days of treatment. The initial treatment plan shall be in effect until the Master Comprehensive Treatment Plan (MCTP) has been developed.

**"Intake"** means the gathering of personally identifying and clinical data required to determine whether a client should be admitted to a program.

**"Intern"** means a student who performs counseling functions under the supervision of a **Clinical Supervisor**.

**"License"** means the document issued by the Division that authorizes a program to provide alcohol and/or other drug treatment or rehabilitation.

**"Licensed Nurse"** means a Registered Nurse or a Licensed Practical Nurse.

**"Licensed Practical Nurse"** means a person licensed by the State of Delaware as a Practical Nurse or a person licensed by a state that participates in the National Licensure Compact (NLC).

**"Licensure"** means the process by which the Division determines whether or not a program is in compliance with these regulations.

**"Master Comprehensive Treatment Plan"** means a treatment plan that is formulated from the comprehensive assessment as outlined in §8.1.2.1.2.14 and in the format outlined in §8.1.2.2.1.

**"Medical history"** means history of and any treatment of allergies, head injuries, nervous disease/disorders, seizure disorder, or delirium tremens, surgery, major accidents, fractures, venereal diseases, cardiovascular, respiratory, endocrine, gastrointestinal diseases or disorders, and gynecological-obstetrical history, including current involvement in prenatal care.

**"Nurse Practitioner"** means a person licensed by the State of Delaware as a Nurse Practitioner or a person licensed by a state that participates in the National Licensure Compact (NLC).

**"Periodic Treatment Plan Review/Revision"** is a process whereby the clinical supervisor and counselor review prior treatment plans and establish new goals based on the client's progress and/or changing needs through out treatment.

**"Physician"** means a person licensed to practice medicine in the State of Delaware.

**"Physician Assistant"** means a person licensed by the State of Delaware as a Physician Assistant.

**"Policy"** means a statement of the principles that guide and govern the activities, procedures and operations of a program.

**"Procedure"** means a series of activities designed to implement the policies of a program.

**"Program"** means the location or facility where an agency provides or offers to provide any of the various modalities of service when such services are provided or offered on a regularly scheduled basis. Clinical participation records of clients are EITHER stored on-site OR readily available to staff in electronic format using computer hardware that is installed or regularly available on-site.

**"Protocols"** means a written rule developed by an agency to govern specific procedures or certain activities.

**"Provisional License"** means the document issue by the Division that authorizes a program to provide alcohol and/or other drug treatment or rehabilitation for up to two hundred forty (240) days when the applicant is not in compliance with these regulations or is applying for licensure for the first time.

**"Public place"** means an area accessible to clients, employees or visitors; the main entry or hallway; the reception area or foyer; or the dining or multipurpose room.

**"Qualified Medical Personnel"** means a physician, physician's assistant, or nurse practitioner, licensed by the State of Delaware.

**"Quality Assurance"** means the process of objectively and systematically monitoring and evaluating the quality and appropriateness of client care to identify and resolve identified issues.

**“Readmission”** means the point in a client’s relationship with an agency when a client has been discharged, subsequently reapplied for admission, intake has been completed, and the agency begins to provide services again.

**“Registered Nurse”** means a person licensed by the State of Delaware as a registered nurse or a person licensed by a state that participates in the National Licensure Compact (NLC).

**“Shall”** means a mandatory procedure, the only acceptable method under these regulations.

**“Signature/Signed”** means, at a minimum, the writers’ first initial, last name, title or credentials and date or an authentic digital signature.

**“Significant other”** means an individual, whether or not related by blood or marriage, on which another individual relies for support.

**“Staff”** means full-time and part-time employees, consultants and volunteers, students/interns.

**“Treatment”** means the process a client undergoes to understand his or her alcohol or drug use and change his or her behavior.

**“Volunteer”** means a person who, without direct financial compensation, provides services to a program.

**“Waiver”** means the exemption from compliance with a requirement of these regulations.

#### **4.0 License Application Procedures**

##### **4.1 Applicability**

4.1.1 Any entity seeking to operate an alcohol and/or other drug abuse treatment or rehabilitation program shall be licensed in accordance with these regulations for each program it seeks to operate. Each facility's license shall list one or more categories of service that the facility is authorized to provide and the facility's location.

4.1.1.1 Program categories for which licenses may be issued are:

- 4.1.1.1.1 Residential Detoxification,
- 4.1.1.1.2 Non-Residential Detoxification,
- 4.1.1.1.3 Outpatient Treatment,
- 4.1.1.1.4 Opioid treatment,
- 4.1.1.1.5 Residential Treatment,
- 4.1.1.1.6 Transitional residential treatment.

##### **4.2 Application Procedures**

4.2.1 The Division shall supply an application packet to all applicants upon request.

4.2.2 All persons and agencies applying for the first time for a license shall schedule a meeting with Division staff for the purpose of receiving needed technical assistance regarding the licensure criteria and procedures.

4.2.3 A separate application shall be completed for each program at each location at which an agency intends to operate a substance abuse program.

4.2.4 The applicant may withdraw the application at any time by notifying the Division in writing.

##### **4.3 Required Information**

4.3.1 An applicant for licensure shall submit the following information on forms provided by the Division:

- 4.3.1.1 Name and address of the applicant;
- 4.3.1.2 Name, address and qualifications of the agency director, Administrator and/or partners, including copies of the professional licenses each has been issued by the State of Delaware;
- 4.3.1.3 Articles of incorporation and bylaws, and/or partnership agreement;
- 4.3.1.4 Name and address, occupation and place of employment, of the Administrator, board members, advisory board members, and officers.
- 4.3.1.5 A chart of the staff organization with names and qualifications;

- 4.3.1.6 A description of the services to be provided by the program, including a statement of the program philosophy, goals, and objectives and a description of the methodology for each service element;
- 4.3.1.7 A copy of the program's complete proposed policies and procedures manual if the application is for initial licensure;
- 4.3.1.8 Documentation of applicable insurance coverage, including protection of the physical and financial resources of the program; coverage for all people, buildings and equipment; professional and general liability insurance; workers' compensation; fidelity bonding sufficient to cover all client funds, property and interests; and automobile insurance when vehicles owned by the program are used for client transportation;
- 4.3.1.9 A floor plan for any facility not previously licensed;
- 4.3.1.10 For residential and detoxification facilities, the maximum client capacity requested; and
- 4.3.1.11 A copy of the program's business license, if required.
- 4.3.2 Applicants applying for Deemed Status shall meet all standards as outlined in Sections 16.0 and 17.0 (as applicable) of these standards.
- 4.3.3 Applicants shall supply all information requested on the application. The completed application shall be accompanied by a \$15.00 fee in accordance with 16 **Del.C.** §2205. The Division shall not consider any application until it is properly completed.
- 4.4 Application Processing
  - 4.4.1 The Division shall determine whether an application is complete and shall notify the applicant in writing if additional information is required to complete the application or determine the applicant's compliance with these regulations.
  - 4.4.2 The Division shall investigate and consider each completed application. An applicant for renewal shall submit its completed application at least ninety (90), but not more than one hundred and twenty (120), days before its current license expires.
- 4.5 Investigations and Inspections
  - 4.5.1 By applying for or accepting a license, an applicant or licensee authorizes the Division and its representatives to conduct the inspections and investigations necessary to determine compliance with applicable licensing standards.
  - 4.5.2 Agencies applying for licensure shall have the following information available for inspection by the Division:
    - 4.5.2.1 Materials demonstrating compliance with all related Federal, State and local statutes, ordinances, rules and regulations [e.g., fire, health, building, American's with Disabilities Act] applicable to the facility being licensed,
    - 4.5.2.2 A copy of the program's policies and procedures manual as required in 5.1.4;
    - 4.5.2.3 Materials demonstrating compliance with the relevant sections of Part III, Provisions Regarding Modalities of these regulations; and
    - 4.5.2.4 Materials demonstrating compliance with all other applicable licensing authorities and accreditation authorities when applicable.
  - 4.5.3 Investigations and inspections may include on-site inspections of the program and its operation; inspection and copying (in accordance with 42 CFR Part 2 and HIPAA 45 CFR Parts 160 and 164) of program records, clinical records and other documents maintained by the program; and acquisition of other information, including otherwise privileged or confidential information from any other persons who may have information bearing on the applicant's or licensee's compliance or ability to comply with these regulations.
  - 4.5.4 The Division shall review, update and when necessary, amend these regulations no less than every three (3) years.
- 4.6 Division Report
  - 4.6.1 Upon completion of any inspection, the Division shall compile a Survey Summary Report citing strengths and deficiencies in meeting these standards.

- 4.6.2 The Division shall schedule an exit interview with each program for review of the Survey Summary Report.
- 4.7 Corrective action plans
  - 4.7.1 Within ten (10) working days after the receipt of a survey summary report, the program shall submit a corrective action plan to the Division, unless otherwise directed by the Division.
  - 4.7.2 The corrective action plan shall include a description of the corrective measures the program will take to address the regulation cited in the survey summary report, a target date for implementation of each corrective measure, and a description of the preventive measures implemented to ensure ongoing compliance with these regulations.
  - 4.7.3 The Division may perform follow-up on-site inspections to review the implementation of corrective action plan(s).
- 4.8 Actions on applications for licensure
  - 4.8.1 On the basis of the information supplied by the applicant and any other information acquired during its investigation and inspection, the Division may take any one of the following actions:
    - 4.8.1.1 Issue or renew a full license for a period of up to two years when the Division determines a program is in substantial compliance with Chapter 22 of Title 16 **Del.C.**, and these regulations, and/or has been granted Deemed Status or
    - 4.8.1.2 Issue or renew a full license for a period of up to one year when the Division determines a program is in compliance with Chapter 22 of Title 16 **Del.C.**, and these regulations;
    - 4.8.1.3 Issue or renew a full license for a period of up to one year when the Division determines a program that has been granted Deemed Status is not in compliance with Chapter 22 of Title 16 **Del.C.** and these regulations or regulations set forth by the accreditation body; or
    - 4.8.1.4 Issue a provisional license for up to two hundred forty (240) days when the applicant is not in compliance with Chapter 22 of Title 16 **Del.C.**, or regulations set forth by the accreditation body upon which Deemed Status has been granted (when applicable) and the applicant's failure to meet the requirements of Chapter 22 of Title 16 **Delaware Code** and these regulations does not jeopardize the health, safety and well-being of clients. The Division may issue one renewal of a provisional license for a period not to exceed two hundred forty (240) days. (The Division's decision to issue a provisional license instead of a full license is final and not subject to administrative appeal;) or
    - 4.8.1.5 Issue a temporary license for up to ninety (90) days when additional time is required by the Division to inspect or investigate the applicant, additional time is required by the applicant to undertake remedial measures or complete a corrective action plan, when the applicant's failure to meet the requirements of Chapter 22 of Title 16 **Delaware Code**, and these regulations does not jeopardize the health, safety and well-being of clients. A temporary license is not renewable and shall expire automatically without notice or hearing. (The Division's decision to issue a temporary license instead of a full or provisional license is final and not subject to administrative appeal,) or
    - 4.8.1.6 Revoke, suspend or deny a license in accordance with 4.9 and 4.10.
  - 4.8.2 The Division may issue a single renewal of a license, for no longer than the term of the current license, without an on site inspection by the Division.
  - 4.8.3 The Division shall notify the applicant by mail, phone, email or any combination of the above of its licensure decision.
- 4.9 Access by the Division
  - 4.9.1 A program is subject to review, which may include on site inspection, with or without notice, by the Division.

- 4.9.2 The Division's right to monitor shall include complete access to all clients and staff, and board members, and to all client, staff, financial and administrative program records needed for the purposes of monitoring or evaluation of the program's compliance with these regulations, financial auditing or for research. The Division may review and copy records in accordance with 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164.
- 4.10 Nonassignability; Change in circumstances; Posting
  - 4.10.1 A license for the operation of a substance abuse program applies to both the applicant program and the premises upon which the program operates. Licenses are not transferable, remain the property of the Division, and shall be returned upon request.
  - 4.10.2 A program's current license shall be posted in a public place at its facility.
  - 4.10.3 The Division issues each license on the basis of information available to it on the date the license is issued. An applicant or licensee shall give written notice to the Division of any change of program name, ownership, governing authority, premises or location a minimum of thirty (30) days before such change takes effect. The Division will determine within fifteen (15) days whether a new application is required.
  - 4.10.4 Any person or entity acquiring a licensed substance abuse program shall apply for a new license in accordance with these regulations.
  - 4.10.5 A licensee shall notify the Division in writing sixty (60) days prior to a voluntary closure of any program it is operating. The notice shall detail how the licensee will comply with 8.1.1.2.
  - 4.10.6 The licensee shall provide written notice to clients no less than thirty (30) days prior to closure and shall make reasonable efforts to place clients in appropriate programs.
- 4.11 Relationship to funding
  - 4.11.1 The issuance of a license to a program is not a commitment of the Division to fund the program.
- 4.12 Reasons for denial, suspension or revocation of license
  - 4.12.1 A license may be denied, suspended or revoked for one or more of the following reasons:
    - 4.12.1.1 When an applicant or program submits false information to the Division for licensing purposes;
    - 4.12.1.2 When an applicant or program fails to cooperate with the Division in connection with a licensing inspection or investigation;
    - 4.12.1.3 When an applicant or program has deviated from the category of service listed on its license;
    - 4.12.1.4 When an applicant or program fails to be in compliance with the requirements of these regulations for the types of services for which application was made or for which the program was licensed, as outlined in 4.8.
    - 4.12.1.5 When an applicant or program fails to implement the corrective action plan it submitted pursuant to 4.7, unless the Division approves an extension or modification of the corrective action plan;
    - 4.12.1.6 When an applicant or program has violated any part of Title 16 **Del.C.**, Chapter 22 or these regulations;
    - 4.12.1.7 When an applicant or program has a history of, or currently demonstrates, financial insolvency, such as
      - 4.12.1.7.1 Filing for bankruptcy;
      - 4.12.1.7.2 Being subjected to foreclosure, eviction for failure to pay rent, or termination of utility services for failure to pay bills; or
      - 4.12.1.7.3 Failing to pay such taxes as employment or social security in a timely manner.
    - 4.12.1.8 When the applicant is in violation of a safety or sanitation law or regulation and fails to correct the violation;
    - 4.12.1.9 When the applicant, its governing body or owner participates in, condones or is associated with fraud, deceit, coercion, misrepresentation or any other illegal act;

- 4.12.1.10 When the applicant, or any of its personnel or governing body violate professional ethics;
  - 4.12.1.11 When the applicant, or any of its personnel or governing body, permits, aids or abets the commission of an unlawful act within its facilities or permits, aids or abets the commission of an unlawful act involving chemical substances within the program; or
  - 4.12.1.12 When the applicant, or any of its personnel or governing body, has participated in, condoned, associated with or knows or should have known and has permitted the continuation of any other practice that jeopardizes the safety or health or well being of any client.
- 4.13 Procedure when a license is denied, suspended or revoked
- 4.13.1 In accordance with 16 **Del.C.** §2208, when the Division determines that an applicant or licensee fails to meet minimum compliance with the requirements of these regulations for the types of services for which application was made or for which the program was licensed or has committed an act or engaged in conduct or practices justifying denial, suspension or revocation of licensure:
    - 4.13.1.1 The Division shall notify the applicant or licensee by certified mail, return receipt requested, of its intent to deny, suspend or revoke the license. The "Notice of Intended Action" shall include the particular reason(s) for the proposed action and provision for a fair hearing.
  - 4.13.2 Within ten (10) days after receipt of the "Notice of Intended Action," an applicant or licensee may request a hearing by delivering a written request to the Division Director in person or by certified mail, return receipt requested. If no such request is made within ten (10) days, the Secretary of the Department shall proceed to deny, revoke or suspend said license as set forth in the notice of proposed action.
  - 4.13.3 Within fifteen (15) days after receipt of an applicant's or licensee's request for a hearing, the Division Director shall issue a "Notice of Hearing" to the applicant or licensee and to the public. The "Notice of Hearing" shall include a statement of the time, place and nature of the hearing, a statement of the legal authority and jurisdiction under which the hearing is to be held; a reference to the particular provisions of the statutes and rules involved; and a short and plain statement of the matters asserted.
  - 4.13.4 All hearings conducted under this subsection shall be governed by procedures authorized by rules of the Department; the Department or its agent may take testimony concerning any matter within its jurisdiction and may administer oaths, summons or subpoenas for any witness and subpoenas duces tecum, which shall be served and returned as provided by law.
  - 4.13.5 At the hearing, the applicant or licensee shall have the right to cross-examine witnesses against it, produce witnesses in its favor and to appear personally or by counsel.
  - 4.13.6 All hearings shall be open to the public and a full record and transcript of the proceedings shall be prepared. The Secretary of the Department shall make a determination, which shall specify the Department's findings of fact and conclusions. A copy of the determination shall be sent by certified mail, return receipt requested, or be personally served upon the applicant or licensee.
  - 4.13.7 Copies of the transcription may be obtained by any interested party on payment of the cost of preparing such copies.
- 4.14 Procedure for reinstatement of suspended or revoked license
- 4.14.1 If the licensee has not previously had a license revoked or suspended under these rules, it may, at any time after the suspension or revocation determination is final, request a hearing for the purpose of showing that the reasons for revocation or suspension of the license have been corrected and that the license should be reinstated.
  - 4.14.2 No licensee who has previously had a license suspended or revoked under these rules may request a hearing to reinstate the license prior to one year after the determination becomes final.



- 4.14.3 The request for a hearing shall be in writing and shall be delivered to the Secretary of the Department in person or by certified mail, return receipt requested.
- 4.14.4 Any hearing conducted under this subsection shall not operate to stay or supersede any decision revoking or suspending a license.
- 4.14.5 Hearings under this subsection shall be conducted in accordance with 29 **Del.C.** §§100 and 101 and 4.13 of these regulations.
- 4.15 Waiver
  - 4.15.1 An application for a waiver from a requirement of these regulations shall be made in writing to the Division's Licensing Unit; it shall specify the regulation from which waiver is sought, demonstrate that each requested waiver is justified by substantial hardship, and describe the alternative practice(s) proposed. The waiver request shall be posted in a prominent place in the facility and outline a process approved by the Division whereby clients can offer comments and feedback specific to the waiver request. The Division's Licensing Unit shall make a recommendation of action on the application after reviewing the waiver request and any client input to the Division Director or designee. Only the Division Director shall grant waivers.
  - 4.15.2 No waiver shall be granted if such action would result in an activity or condition that would endanger the health, safety or well-being of a client.
  - 4.15.3 RESERVED.
  - 4.15.4 A waiver granted under these regulations shall be in effect for the term of the applicant's license unless the approval of the waiver specifies a shorter term. All waivers not otherwise approved for a shorter term shall expire at the end of the term of the license and new waiver(s) must be requested as part of the licensure renewal process in accordance with 4.15.
  - 4.15.5 An adverse decision by the Division on a request for a waiver may be appealed in accordance with 4.13.
  - 4.15.6 The granting of a waiver does not constitute a modification of any requirement of these regulations.
  - 4.15.7 Licensees shall notify the Division within ten (10) working days when a waiver granted by the Division is no longer needed.
  - 4.15.8 The Division Director may revoke a waiver when the alternative practice proposed in the application for waiver is determined to be ineffectual.
  - 4.15.9 The Division Director may revoke the waiver when the program fails to implement the alternative practice as proposed in the application for waiver.

## **Part II--General Provisions**

### **5.0 Standards Applicable to all Facilities and Programs**

- 5.1 Governance
  - 5.1.1 Governing Body/Advisory Council.
    - 5.1.1.1 Every community-based agency shall have a governing body and/or advisory council that includes representatives of the population it serves.
    - 5.1.1.2 The governing body shall be legally responsible for overseeing all management and operations of the agency and for ensuring compliance with applicable laws and regulations by approving all of the agency's staffing, documentation and overall operations:
      - 5.1.1.2.1 Written by-laws;
      - 5.1.1.2.2 Mission;
      - 5.1.1.2.3 Goals;
      - 5.1.1.2.4 Policies and Procedures; and
      - 5.1.1.2.5 Budget.
  - 5.1.1.3 The authority and duties of the governing body shall include:

- 5.1.1.3.1 Ensuring that the agency director, Administrators, clinical supervisors and counselors employed by the agency meet the requirements of 6.1 of these regulations.
- 5.1.1.3.2 Establishing and reviewing:
  - 5.1.1.3.2.1 policies and procedures governing the overall management of the program including:
    - 5.1.1.3.2.1.1 policies and procedures manual; (5.1.4),
    - 5.1.1.3.2.1.2 fiscal management policies and procedures; (5.1.5),
    - 5.1.1.3.2.1.3 personnel policies and procedures; (5.1.6.2), and 5.1.1.3.2.1.4 compliance with these regulations.
- 5.1.1.4 The Governing Body will meet, at a minimum, one (1) time per year. Documentation of its annual review shall be entered into the minutes of its meeting.
- 5.1.2 Meetings and minutes of meetings.
  - 5.1.2.1 Minutes of all meetings shall include:
    - 5.1.2.1.1 Names of members who attended;
    - 5.1.2.1.2 Names of members absent;
    - 5.1.2.1.3 Date of meeting;
    - 5.1.2.1.4 Topics discussed and decisions reached.
  - 5.1.2.2 The minutes shall be available for review by the Division.
- 5.1.3 Administrative Staff
  - 5.1.3.1 Administrator
    - 5.1.3.1.1 The governing body shall appoint an agency director.
    - 5.1.3.1.2 The qualifications, authority, and duties of the agency director shall be defined in writing.
    - 5.1.3.1.3 The Governing body shall ensure that, at the time of employment, the agency director is familiar with the job description and job responsibilities of the position, these regulations, and the agency's policies and procedures as maintained in compliance with 5.1.4.
- 5.1.4 Policies and procedures manual:
  - 5.1.4.1 Each program shall have a manual of written policies from which written procedures have been derived to address operations and services. The program's policies and procedures manual shall be:
    - 5.1.4.1.1 A complete document;
    - 5.1.4.1.2 Readily available to staff.
  - 5.1.4.2 The program's policies and procedures manual shall be reviewed at least annually by the governing body or its designee.
  - 5.1.4.3 The review shall be documented in the meeting minutes.
  - 5.1.4.4 The manual shall include:
    - 5.1.4.4.1 A statement of program philosophy and goals, including:
      - 5.1.4.4.1.1 geographical area to be served;
      - 5.1.4.4.1.2 population to be served;
      - 5.1.4.4.1.3 types of services offered;
      - 5.1.4.4.1.4 organization chart,
      - 5.1.4.4.1.5 Policies and procedures to ensure compliance with 5.1.5, Fiscal management;
      - 5.1.4.4.1.6 Policies and procedures to ensure compliance with 5.1.6.2, Personnel;
      - 5.1.4.4.1.7 The intake procedures

- 5.1.4.4.1.8 The assessment procedure established by the Administrator in compliance with 8.1.2.1.2.14.
- 5.1.4.4.1.9 Referral criteria policies and procedures.
- 5.1.4.4.1.10 Admission criteria policies and procedures;
- 5.1.4.4.1.11 Discharge criteria policies and procedures that specify conditions under which clients may be involuntarily discharged, including client behavior that constitutes grounds for discharge by the program.
- 5.1.4.4.1.12 Established procedures consistent with 42 CFR §2.12(c)(5) and HIPAA 45 CFR parts 160 and 164 that staff shall follow when discharging a client involved in the commission of a crime on the premises of the program or against its staff, including designation of the person who shall make a report to the appropriate law enforcement program;
- 5.1.4.4.1.13 Established procedures consistent with 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164 that staff shall follow when a client leaves against medical or staff advice and the client may be dangerous to self or others;
- 5.1.4.4.1.14 Confidentiality policy and procedures that comply with 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164;
- 5.1.4.4.1.15 Policies and procedures in regard to completion and utilization of all forms used by the program;
- 5.1.4.4.1.16 Policies and procedures for making mandated reports of suspected child abuse or neglect in compliance with 16 **Del.C.** §§902 through 904, and 42 CFR § 2.12(c)(6);
- 5.1.4.4.1.17 Policies and procedures for communicating with law enforcement personnel when a client commits or threatens to commit a crime on program premises or against program personnel, in compliance with 42 CFR § 2.12(c)(5) and HIPAA 45 CFR parts 160 and 164;
- 5.1.4.4.1.18 Policies and procedures for mandated reporting of infectious or contagious diseases, in compliance with state law and 42 CFR Part 2 and HIPAA 45 CFR Parts 160 and 164;
- 5.1.4.4.1.19 Medication policies and procedures, in compliance with the Delaware State Boards of Medical Practice, Nursing, and Pharmacy;
- 5.1.4.4.1.20 Policies and procedures, as applicable, for the collection of urine specimens;
- 5.1.4.4.1.21 Policies and procedures for responding to medical emergencies;
- 5.1.4.4.1.22 Policies and procedures regarding clients' rights
- 5.1.4.4.1.23 Code of ethics; and
- 5.1.4.4.1.24 Policies and procedures for reporting any violations of law or codes of ethics to the appropriate certification and/or licensure boards.
- 5.1.5 Fiscal management policies and procedures and record keeping
  - 5.1.5.1 Each program shall establish written policies and procedures regarding fiscal management that shall be maintained in compliance with generally accepted accounting principles.
- 5.1.6 Personnel policies and procedures.
  - 5.1.6.1 Each program shall develop and maintain a written personnel manual that shall include:
    - 5.1.6.1.1 Staff rules of conduct consistent with due process including:
    - 5.1.6.1.2 Examples of conduct that constitute grounds for disciplinary action;
    - 5.1.6.1.3 Examples of unacceptable performance that constitute grounds for disciplinary action;
    - 5.1.6.1.4 Policies and procedures on mental health, and alcohol and drug abuse problems of staff (including staff member assistance policies and procedures);
    - 5.1.6.1.5 Safety and health of staff, including:

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- 5.1.6.1.6 Rules about any required medical examinations and rules about communicable diseases that could affect the health or safety of the program's clients or staff.
- 5.1.6.2 Each agency shall maintain a separate personnel file for each staff member in a manner that ensures the privacy of agency staff.
- 5.1.6.3 The personnel file shall include at a minimum:
  - 5.1.6.3.1 the name and telephone number of a person the agency can contact in an emergency;
  - 5.1.6.3.2 The current job title and job description signed by the staff member;
  - 5.1.6.3.3 Either:
    - 5.1.6.3.3.1 an application for employment signed by the staff member; or
    - 5.1.6.3.3.2 a resume;
  - 5.1.6.3.4 A copy of the staff member's license and/or current alcohol or other drug counselor certification.
  - 5.1.6.3.5 The results of reference investigations and verification of experience, training and education, including:
    - 5.1.6.3.5.1 primary source verification of the staff member's educational degree certificate(s), based on job description;
    - 5.1.6.3.5.2 primary source verification of the staff member's license(s), and/or certification(s), as applicable, based on job description;
    - 5.1.6.3.5.3 A statement signed by the staff member acknowledging that s/he understands the requirements of 42 USC §290dd-2, 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164;
    - 5.1.6.3.5.4 Documentation of the staff member's annual written performance evaluation;
    - 5.1.6.3.5.5 any disciplinary actions taken against the staff member;
    - 5.1.6.3.5.6 formal corrective action taken, that:
      - 5.1.6.3.5.6.1 the staff member has signed;
      - 5.1.6.3.5.6.2 his/her immediate supervisor has signed;
    - 5.1.6.3.5.7 A copy of the staff member's training plan, as required in 5.1.7.1;
    - 5.1.6.3.5.8 Documentation of the staff member's abilities to provide culturally competent services; and
    - 5.1.6.3.5.9 Documentation of in-service training and continuing education as required by 5.1.7.
  - 5.1.6.3.6 Criminal background checks and previous, substantiated reports to the Adult Abuse and Child Abuse registries,
- 5.1.6.4 Counselor II's personnel files shall also include:
  - 5.1.6.4.1 Documentation that the Counselor II is working toward meeting the requirements of 6.1.5; and
  - 5.1.6.4.2 Documentation of Supervision as required in 6.1.5.2 and 6.1.5.3.
- 5.1.6.5 Records documenting all required staff member health clearances, including any medical test results required by agency policy shall be made available to the Division upon request.
- 5.1.7 Staff training and development
  - 5.1.7.1 Each program shall establish a written staff training and development plan. The plan shall include:
    - 5.1.7.1.1 An orientation curriculum, that will ensure that all staff are familiar with the agency policies and procedures, and have a working knowledge of at least the following:
      - 5.1.7.1.1.1 personnel policies and procedures, regarding the health and safety of staff, established in compliance with 5.1.6.1.5;

- 5.1.7.1.1.2 program policies and procedures regarding the reporting of cases of suspected child abuse or neglect in compliance with 16 Del.C. §§902 through 904 and 16 Del.C. §2224;
- 5.1.7.1.1.3 program policies and procedures regarding client's rights established in compliance with 7.0, as applicable;
- 5.1.7.1.1.4 instruction and training in the elements of the fire plan in compliance with 9.2;
- 5.1.7.1.1.5 program policies and procedures regarding the obligation to report violations of law and applicable codes of ethics to the appropriate certification and/or licensure boards, established in compliance with 5.1.4.4.1.24.
- 5.1.7.1.1.6 program policies and procedure regarding the training of all staff regarding culturally competent practices.
- 5.1.7.2 Programs shall annually establish an individual training plan for each staff member based on the staff member's skill level, education, experience, current job functions, and job performance.
- 5.1.7.3 Clinical supervisors and all staff providing counseling services to clients shall complete at least twenty (20) hours of training annually, including:
  - 5.1.7.3.1 Ten (10) hours specific to training and education in the treatment of alcohol and other drugs of abuse; and
  - 5.1.7.3.2 Three (3) hours specific to training and education in providing culturally competence services.
  - 5.1.7.3.3 Three (3) hours of training specific to ethics training and education.
- 5.1.7.4 Adjunctive and Alternative Therapies
  - 5.1.7.4.1 Every program utilizing any modalities of adjunct or alternative therapy shall ensure:
    - 5.1.7.4.1.1 Adjunctive or Alternative Therapies are approved by the Administrator or designee prior to utilization;
    - 5.1.7.4.1.2 individuals providing the services of Adjunctive or Alternative Therapies have received specific training and/or credentials applicable to each modality;
- 5.1.7.5 All staff, trainees and volunteers shall receive training within the first year of employment about:
  - 5.1.7.5.1 Hepatitis;
  - 5.1.7.5.2 HIV/AIDS;
  - 5.1.7.5.3 Tuberculosis;
  - 5.1.7.5.4 Other sexually transmitted diseases;
- 5.1.8 Quality Assurance
  - 5.1.8.1 Every agency shall have a written quality assurance plan.
  - 5.1.8.2 The plan shall be reviewed and revised annually.
  - 5.1.8.3 The quality assurance plan shall provide for the review of:
    - 5.1.8.3.1 Clinical services to include:
      - 5.1.8.3.1.1 The provision of culturally competent services including:
        - 5.1.8.3.1.1.1 An annual self assessment that focuses on the needs of the community which the agency serves;
    - 5.1.8.3.2 Professional services;
    - 5.1.8.3.3 Administrative services;
    - 5.1.8.3.4 Infection Control; and
    - 5.1.8.3.5 Environment of Care.
  - 5.1.8.4 The results of quality assurance review shall document:
    - 5.1.8.4.1 The problem(s) identified;
    - 5.1.8.4.2 The recommendations made;

- 5.1.8.4.3 The action(s) taken;
- 5.1.8.4.4 The individual(s) responsible for implementation of actions; and
- 5.1.8.4.5 Any follow-up.
- 5.1.8.5 Every agency shall develop and implement performance indicators and assess outcome measures.
- 5.1.8.6 Every program shall provide a mechanism to collect opinions from service recipients regarding the quality of service provided. Information shall be submitted to the appropriate committee for quality assurance review.

## **6.0 Standards Applicable to all Facilities and Programs**

### **6.1 Staff Qualifications**

#### **6.1.1 Qualifications for the Position of Administrator**

- 6.1.1.1 Each agency shall have an administrator responsible for the overall management of the agency and/or program and staff.
- 6.1.1.2 Each administrator hired or promoted on or after the date these regulations become effective shall have at a minimum:
  - 6.1.1.2.1 A Bachelor's Degree from an accredited college or university with at least 5 years of documented experience in human services including:
    - 6.1.1.2.1.1 at least two (2) years of experience in substance abuse treatment; and
    - 6.1.1.2.1.2 at least two (2) years of management experience.

#### **6.1.2 Qualifications for the Position of Clinical Director**

- 6.1.2.1 Each individual, hired or promoted, to the position of Clinical Director on or after the date these regulations become effective shall have, at a minimum:
  - 6.1.2.1.1 A master's degree with a major in chemical dependency, psychology, social work, in counseling, nursing or a related field of study and five (5) years of documented clinical experience in human services, at least three (3) years of which shall be in substance abuse services; or
  - 6.1.2.1.2 A Bachelor's Degree from an accredited college or university with a major in chemical dependency, psychology, social work, counseling, nursing or a related field, full certification as an alcohol and drug counselor and five (5) years of clinical experience in the substance abuse treatment field, including two years of management experience.

#### **6.1.3 Qualifications for the Position of Clinical Supervisor**

- 6.1.3.1 Each individual authorized, hired, or promoted, to provide clinical supervision on or after the date these regulations become effective shall meet one of the following:
  - 6.1.3.1.1 A Bachelor's Degree from an accredited college or university with a major in chemical dependency, psychology, social work, counseling, or nursing or a related field of study and full certification as a certified alcohol and drug counselor (CADC) in the state of Delaware or by a nationally recognized organization in addictions counseling; or
  - 6.1.3.1.2 A Bachelor's Degree from a accredited college or university with a major in chemical dependency, psychology, social work, counseling, or nursing or a related field of study and five (5) years of documented clinical experience in the substance abuse treatment field.

#### **6.1.4 Qualifications for the Position of Counselor I**

- 6.1.4.1 Each individual hired or promoted on or after the date these regulations become effective shall meet one of the following requirements:
  - 6.1.4.1.1 Full certification as a certified alcohol and drug counselor (CADC) in the state of Delaware; or
  - 6.1.4.1.2 Full certification by a nationally recognized body in addictions counseling; or

- 6.1.4.1.3 Five (5) years of documented clinical experience working in the field of substance abuse treatment.
- 6.1.5 Counselor II
  - 6.1.5.1 Qualifications for the Position of Counselor II
    - 6.1.5.1.1 A person who does not meet the educational and experiential qualifications for the position of Counselor I as set forth in 6.1.4 may be employed as a Counselor II if the individual holds a minimum of a high school diploma or its equivalent and meets at least one of the following:
      - 6.1.5.1.1.1 The individual has less than five (5) years of documented clinical experience working in the substance abuse treatment field.
      - 6.1.5.1.1.2 The individual is a student enrolled in a course of study while completing a practicum or internship;
      - 6.1.5.1.1.3 The individual is working toward full certification in addictions counseling by the Delaware Certification Board or a nationally recognized organization in addictions counseling.
    - 6.1.5.2 The individual must receive clinical supervision by the Clinical Supervisor a minimum of one (1) hour per every twenty (20) hours of clinical services provided to clients.
    - 6.1.5.3 The Clinical Supervisor must review all documentation developed by the Counselor II for accuracy and clinical appropriateness.
- 6.1.6 Individuals appropriately hired, authorized or promoted to function as a Clinical Director, Clinical Supervisor or Counselor I or II prior to the date these regulations become effective and who met the standard(s) for such functions existing prior to the date these regulations become effective, but who do not meet the requirements set forth in this section, may continue to function in their current role as a Clinical Director, Clinical Supervisor or Counselor I or II.

## **7.0 Standards Applicable to all Facilities and Programs**

- 7.1 Clients' Rights
  - 7.1.1 Nondiscrimination policy
    - 7.1.1.1 No program shall deny any person equal access to its facilities or services on the basis of race, color, religion, ancestry, sexual orientation, gender expression, national origin, or disability.
    - 7.1.1.2 No program shall deny any person equal access to its facilities or services on the basis of age or gender, except those programs that specialize in the treatment of a particular age group (such as adolescents) or gender (such as mothers and infants).
    - 7.1.1.3 All agencies shall ensure that they comply with the federal Americans with Disabilities Act, 28 U.S.C. §§12101 et seq. and 28 Code of Federal Regulations, Part 36 (July 1991) and 16 Del.C. §2220.
  - 7.1.2 Enumerated Rights
    - 7.1.2.1 All agencies shall ensure that clients' rights are fully protected, including the following:
      - 7.1.2.1.1 To be free from retaliation for exercising any enumerated right.
      - 7.1.2.1.2 To file a grievance or complaint with the program in accordance with its policy and procedures. Procedures for receiving, investigating, hearing, considering, responding to and documenting grievances shall:
        - 7.1.2.1.2.1 Include a procedure for receipt of grievances from clients or persons acting on their behalf;
        - 7.1.2.1.2.2 Provide for the investigation of the facts supporting or disproving the grievance;
        - 7.1.2.1.2.3 Identify the staff responsible for receipt and investigation of grievances;

- 7.1.2.1.2.4 Be posted in a public place;
- 7.1.2.1.3 Participate, and/or have others of his/her choice participate, in an informed way in the grievance process.
- 7.1.2.1.4 To be informed that participation in treatment is voluntary, except as provided in 16 **Del.C.** §§2211, 2212, 2213 and 2215.
- 7.1.2.1.5 To refuse service, except as provided in 16 **Del.C.** §§2211, 2212, 2213 and 2215. If consequences, such as termination from other services, may result from such refusal, that fact shall be:
  - 7.1.2.1.5.1 Documented in the client's file.
- 7.1.2.1.6 To be free of any exploitation or abuse by any program personnel or any member of the governing body.
- 7.1.2.1.7 To be assured that any incident of abuse; neglect or mistreatment will be reported in accordance with 5.1.4.4.1.16.
- 7.1.2.1.8 To communicate with legal counsel.
- 7.1.2.1.9 To confidentiality of all records, correspondence and information relating to assessment, diagnosis and treatment in accordance with 42 U.S.C. § 290dd-2, 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164.
- 7.1.2.1.10 To review his/her own records in accordance with 42 U.S.C. § 290dd-2, 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164.
- 7.1.2.1.11 Client request for review and a summary of the review if granted shall be documented in the client's record.
- 7.1.2.2 Participation in experimental or research programs
  - 7.1.2.2.1 No client shall participate in any experimental or research project without the full knowledge, understanding and written consent of that client (and/or legal guardian, when appropriate).
  - 7.1.2.2.2 All experimental or research projects shall be conducted in full compliance with applicable state and federal laws, regulations and guidelines.
- 7.1.3 Barriers to treatment:
  - 7.1.3.1 The program shall make reasonable modifications in policies, practices and procedures and/or provide assistive services to accommodate clients who are unable to participate in treatment due to language, cultural, literacy barriers or disabilities.

## **8.0 Standards Applicable to all Facilities and Programs**

- 8.1 Clinical records
  - 8.1.1 Maintenance of client records
    - 8.1.1.1 Programs shall:
      - 8.1.1.1.1 Maintain a record for each client that is
        - 8.1.1.1.1.1 accurate,
        - 8.1.1.1.1.2 legible and
        - 8.1.1.1.1.3 signed by the staff member who provided the service.
    - 8.1.1.1.2 Maintain a standardized client record-keeping system, with client records that are uniform in format and content;
    - 8.1.1.1.3 Establish and maintain a system that permits easy identification of and access to individual client records by authorized program staff;
    - 8.1.1.1.4 Comply fully with the provisions of 42 U.S.C. § 290dd-2 and 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164;
    - 8.1.1.1.5 Update each record within twenty-four (24) hours of delivery of a service unless otherwise specified in these regulations.
  - 8.1.1.2 Any program that discontinues operations, or is merged with, or acquired by another program is responsible for ensuring compliance with the requirements of



42 CFR § 2.19, and HIPAA 45 CFR parts 160 and 164 whichever is applicable.

The program shall document in writing to the Division:

8.1.1.2.1 How it will adhere to 42 CFR § 2.19 and HIPAA 45 CFR parts 160 and 164 at the time it notifies the Division of the program closure in accordance with 4.10.5 of these regulations; and

8.1.1.2.2 How it will adhere to 8.0 of these regulations.

8.1.2 Content of Client records

8.1.2.1 A record shall be established for each client upon admission and shall include:

8.1.2.1.1 A Consent to Treatment form signed by the client and, if the client is a minor, the client's parent or guardian, except as provided in 16 **Del.C.** §2210(b).

8.1.2.1.2 An up-to-date face sheet including the client's:

8.1.2.1.2.1 date of admission;

8.1.2.1.2.2 name;

8.1.2.1.2.3 address;

8.1.2.1.2.4 telephone number;

8.1.2.1.2.5 gender;

8.1.2.1.2.6 date of birth;

8.1.2.1.2.7 the client's significant medical history documenting:

8.1.2.1.2.7.1 current medical conditions;

8.1.2.1.2.7.2 any medications the client is currently prescribed;

8.1.2.1.2.7.3 any medications the client is currently taking;

8.1.2.1.2.7.4 allergies,

8.1.2.1.2.8 the name and telephone number of the person to contact in an emergency;

8.1.2.1.2.9 an attached Consent to Release Information form permitting the program to make that contact;

8.1.2.1.2.10 Appropriate Consent to Release Information forms.

8.1.2.1.2.11 Documentation, signed by the client:

8.1.2.1.2.11.1 Acknowledging receipt of the notice of clients' rights;

8.1.2.1.2.11.2 Acknowledging his/her understanding of the agency's agreement with the confidentiality requirements of 7.1.2.1.9;

8.1.2.1.2.11.3 Acknowledging receipt of the program's procedures when an emergency occurs outside of the program's hours of operation.

8.1.2.1.2.12 Copies of any laboratory reports and drug tests ordered by the program.

8.1.2.1.2.13 Informed consent regarding prescribed pharmacotherapy obtained from the client prior to delivery of the medication prescription.

8.1.2.1.2.14 Results of the client's assessment, including the client's:

8.1.2.1.2.14.1 mental health status;

8.1.2.1.2.14.2 psychiatric history;

8.1.2.1.2.14.3 medical history (including allergies);

8.1.2.1.2.14.4 education;

8.1.2.1.2.14.5 work history;

8.1.2.1.2.14.6 criminal justice history;

8.1.2.1.2.14.7 substance use history, including:

8.1.2.1.2.14.7.1 types;

8.1.2.1.2.14.7.2 quantity;

8.1.2.1.2.14.7.3 route;

8.1.2.1.2.14.7.4 frequency of substances used;

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- 8.1.2.1.2.14.7.5 age of first use;
  - 8.1.2.1.2.14.7.6 date of last use;
  - 8.1.2.1.2.14.7.7 duration and patterns of use, including;
    - 8.1.2.1.2.14.7.7.1 periods of abstinence; and
    - 8.1.2.1.2.14.7.7.2 previous treatment episodes and type of discharge;
  - 8.1.2.1.2.14.8 reason(s) for seeking treatment;
  - 8.1.2.1.2.14.9 identification and evaluation of the client's needs
  - 8.1.2.1.2.14.10 Family History including:
    - 8.1.2.1.2.14.10.1 psychiatric history;
    - 8.1.2.1.2.14.10.2 use of alcohol and other drugs by family members and significant others;
  - 8.1.2.1.2.15 Copies of all correspondence related to the client;
  - 8.1.2.1.2.16 A diagnostic assessment summary of the client's status that addresses the client's:
    - 8.1.2.1.2.16.1 strengths;
    - 8.1.2.1.2.16.2 limitations; and
    - 8.1.2.1.2.16.3 goals;
  - 8.1.2.1.2.17 Indicates which issues and areas of clinical concern are to be:
    - 8.1.2.1.2.17.1 treated;
    - 8.1.2.1.2.17.2 deferred; or
    - 8.1.2.1.2.17.3 referred;
  - 8.1.2.1.2.18 Includes the client's:
    - 8.1.2.1.2.18.1 primary language;
    - 8.1.2.1.2.18.2 cultural background;
    - 8.1.2.1.2.18.3 attitudes toward alcohol and other drug use; and spiritual or religious beliefs;
  - 8.1.2.1.2.19 the rationale for placement recommendations; and is:
    - 8.1.2.1.2.19.1 signed by the counselor completing the assessment;
    - 8.1.2.1.2.19.2 reviewed, as indicated by the signature of the clinical supervisor; and
    - 8.1.2.1.2.19.3 Is completed prior to the development of the comprehensive treatment plan.
  - 8.1.2.1.2.20 Name, address and telephone number of most recent primary care provider.
- 8.1.2.2 An individualized Master Comprehensive Treatment Plan, developed in partnership with the client, shall be completed no later than the time required in these regulations for the modality for which the program is licensed.
- 8.1.2.2.1 The treatment plan shall:
- 8.1.2.2.1.1 identify the date the plan is to be effective;
  - 8.1.2.2.1.2 identify the client's:
    - 8.1.2.2.1.2.1 strengths;
    - 8.1.2.2.1.2.2 weaknesses; and
    - 8.1.2.2.1.2.3 any limitations that could be a barrier to treatment.
  - 8.1.2.2.1.3 address the issue(s) to be treated as derived from the assessment process;
  - 8.1.2.2.1.4 identify long term treatment goals based on the assessment of the client;
  - 8.1.2.2.1.5 identify short term treatment goals based on the assessment of the client;
  - 8.1.2.2.1.6 identify objectives that:

- 8.1.2.2.1.6.1 address the goals
- 8.1.2.2.1.6.2 are specific;
- 8.1.2.2.1.6.3 are measurable;
- 8.1.2.2.1.6.4 are time limited; and
- 8.1.2.2.1.6.5 specify the treatment regimen, including:
  - 8.1.2.2.1.6.5.1 which services and/or activities will be used to achieve each treatment plan objective;
  - 8.1.2.2.1.6.6 the frequency of each service and/or activity;
- 8.1.2.2.1.7 be signed by:
  - 8.1.2.2.1.7.1 the client;
  - 8.1.2.2.1.7.2 the staff who developed the treatment plan; and
  - 8.1.2.2.1.7.3 the clinical supervisor;
- 8.1.2.3 Periodic Treatment Plan Review/Revision
  - 8.1.2.3.1 Treatment plans shall be reviewed and revised by the client and his/her counselor no less often than the intervals specified for the modality for which the program is licensed and shall address the issues remaining to be treated as derived from and treatment plan review.
- 8.1.2.4 Progress notes
  - 8.1.2.4.1 Each contact made with or on behalf of the client shall be documented in the client file; and
    - 8.1.2.4.1.1 Be written to include:
      - 8.1.2.4.1.1.1 the type(s) of service provided;
      - 8.1.2.4.1.1.2 the date of the service(s) provided;
      - 8.1.2.4.1.1.3 the length of the service(s) provided; and
      - 8.1.2.4.1.1.4 a description of the client's response to the session including:
        - 8.1.2.4.1.1.4.1 facts:
          - 8.1.2.4.1.1.4.1.1 a description of the service and/or activity; and
          - 8.1.2.4.1.1.4.1.2 the client's participation in the service and/or activity;
        - 8.1.2.4.1.1.4.2 clinical impressions:
          - 8.1.2.4.1.1.4.2.1 the counselor's assessment of the client's response or lack of response to the service and/or activity; and
          - 8.1.2.4.1.1.4.2.2 the client's progress or lack of progress toward achieving the objectives prescribed in the treatment plan;
        - 8.1.2.4.1.1.4.3 plan for future sessions:
          - 8.1.2.4.1.1.4.3.1 anticipated implementation, by the counselor, of services and/or activities as prescribed in the treatment plan.
- 8.1.2.5 Clinical Supervision
  - 8.1.2.5.1 The clinical supervisor shall review each individual client record with the client's primary Counselor as often as necessary, and in conjunction with treatment plan review and revision and no less often than at the intervals specified by each modality for which the program is licensed.
  - 8.1.2.5.2 The clinical supervisor shall provide specific, written clinical recommendations on how to proceed with the case.
  - 8.1.2.5.3 The clinical supervisor shall sign the review.
- 8.1.2.6 Discharge Plan
  - 8.1.2.6.1 In anticipation of successful completion or planned interruption of a client's treatment, the treatment staff and client shall jointly develop a discharge plan.
- 8.1.2.7 Discharge Summary

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- 8.1.2.7.1 For every client that is discharged, the program shall complete a discharge summary within seventy-two (72) hours of a planned discharge and within ninety-six (96) hours of an unplanned discharge.
- 8.1.2.7.2 The narrative discharge summary shall include the client's:
  - 8.1.2.7.2.1 name;
  - 8.1.2.7.2.2 discharge address;
  - 8.1.2.7.2.3 discharge telephone number;
  - 8.1.2.7.2.4 admission date;
  - 8.1.2.7.2.5 discharge date;
  - 8.1.2.7.2.6 a summary of the client's progress toward treatment plan objectives;
  - 8.1.2.7.2.7 a summary of the client's participation in treatment;
  - 8.1.2.7.2.8 the reasons for discharge;
  - 8.1.2.7.2.9 any unresolved issues;
  - 8.1.2.7.2.10 recommendations regarding the need for additional treatment services;
- 8.1.2.7.3 When the discharge is planned, the discharge summary shall be signed by:
  - 8.1.2.7.3.1 the client
  - 8.1.2.7.3.2 the counselor, and
  - 8.1.2.7.3.3 the clinical supervisor.
- 8.1.3 Programs shall provide a list of referral sources for the client's various needs when the agency is unable to meet the client's needs internally. The agency shall be responsible for assisting the client in enrolling in services at other agencies.
- 8.1.4 Programs shall provide a minimum of twelve (12) months of records up until and including the expiration date of the current license for the purposes of licensure audit. Programs shall develop a policy that clearly outlines timelines for record retention and storage for all records beyond the required audit period.

**9.0 Standards Applicable to all Facilities and Programs****9.1 Facility Standards**

- 9.1.1 Unless otherwise specified programs shall be in compliance with the regulations in this section.
- 9.1.2 Each agency shall provide facilities that:
  - 9.1.2.1 provide privacy of communications between clients and staff members;
  - 9.1.2.2 provide waiting areas and meeting spaces that are welcoming to diverse populations and cultures;
  - 9.1.2.3 Include rest rooms for clients, visitors and staff.
- 9.1.3 Agencies shall maintain up-to-date documentation verifying that they have a certificate of occupancy and meet applicable federal, state and local building, zoning, fire, safety and accessibility requirements.
- 9.1.4 Agencies shall maintain facilities in neat and clean condition, and eliminate any hazardous conditions that endanger the health or safety of clients, visitors or staff.
- 9.1.5 Agencies shall not permit tobacco use in program facilities.
- 9.1.6 Agencies shall post a current fee schedule in a public place within the facility.
- 9.1.7 Agencies shall post hours of operation in a public place within the facility.

**9.2 Fire Prevention and Safety**

- 9.2.1 Agencies shall display up to date certificates or approval/inspection by Fire Department authorities whenever this is required/available in the specific community where the program is located.

**9.3 Emergency policies and procedures.**

- 9.3.1 Each agency shall establish a plan of action in the event of emergencies or disasters, based on the program's capability and limitations. The plan shall include provisions:
  - 9.3.1.1 For responding to severe weather, loss of power or water or other natural disaster;
  - 9.3.1.2 For evacuation plans with specific primary and alternative evacuation routes;
  - 9.3.1.3 For posting evacuation routes in areas visible to staff, clients and visitors;
  - 9.3.1.4 For responding to accidents that result in injury or death;
  - 9.3.1.5 Governing how available resources will be used to continue client care;
  - 9.3.1.6 Governing how the program will effectively activate community resources to prevent or minimize the consequences of a disaster;
  - 9.3.1.7 Concerning staff preparedness and the designation of roles and functions;
  - 9.3.1.8 Concerning criteria for the cessation of nonessential services and client transfer determinations; and
  - 9.3.1.9 Governing how it will protect the safety of clients and staff and the security of its records.
- 9.3.2 All treatment programs shall develop procedures for handling a client who is exhibiting behavior that is threatening to the life or safety of the client or others.
- 9.3.3 All treatment programs shall have a staff member on site at all times trained in:
  - 9.3.3.1 Crisis intervention; and
  - 9.3.3.2 The standard Red Cross first aid class and CPR certification, or its equivalent.

### **Part III--Provisions Regarding Modalities**

#### **10.0 Standards Applicable to Residential Detoxification**

- 10.1 Services Required:
  - 10.1.1 In addition to the requirements applicable to all programs, a Medically Monitored Residential Detoxification program shall provide:
    - 10.1.1.1 Meals in accordance with 12.3.
    - 10.1.1.2 Housing in accordance with 12.4.
    - 10.1.1.3 Admission assessment by qualified medical personnel or licensed nurse prior to admission to determine need for detoxification.
  - 10.1.2 There shall be no administration of prescription or non-prescription drugs until qualified medical personnel have examined the client, or qualified medical personnel have been consulted.
  - 10.1.3 Physical examination conducted by qualified medical personnel within twenty-four (24) hours of admission.
  - 10.1.4 A medical care plan within twenty-four (24) hours of admission based on the findings of the physical examination in 10.1.3.
  - 10.1.5 Within Seventy-two (72) hours of admission, assessment in accordance with 8.1.2.1.2.14.
  - 10.1.6 Within seventy-two (72) hours of admission, treatment planning in accordance with 8.1.2.2.
  - 10.1.7 Treatment plan review/revision in accordance with 8.1.2.3.
    - 10.1.7.1 by the 7<sup>th</sup> day, and
    - 10.1.7.2 every 5<sup>th</sup> day thereafter.
  - 10.1.8 For those clients not medically restricted individual counseling that shall include at least one (1) thirty-minute (30) counseling session per day led by a Counselor I or Counselor II.
  - 10.1.9 Group counseling that shall include at least one (1) sixty-minute (60) counseling session per day with a Counselor I or Counselor II.
  - 10.1.10 Emergency medical and hospital services at a licensed hospital, as needed.
- 10.2 Required Additional Policies and Procedures

10.2.1 The program shall have protocols developed and supported by a physician knowledgeable in addiction medicine setting forth:

10.2.1.1 A medication policy that complies with 5.1.4.4.1.19.

10.2.1.2 The protocol staff should take to respond to medical complications throughout the detoxification process.

10.2.1.3 The circumstances under which medical intervention is required.

**10.3 Operation, Staffing and Staff Schedules**

10.3.1 The program shall operate seven (7) days per week, twenty-four (24) hours per day.

10.3.2 The program shall have written affiliation agreements for the provision of services required by this section, when those services are not provided in house.

10.3.3 A physician(s) shall provide on-site services as necessary and on-call services twenty-four (24) hours a day.

10.3.4 When clients are present, there shall be qualified medical personnel or a licensed nurse on site who has knowledge of the complications associated with withdrawal.

10.3.5 When clients are present, there shall be staff on duty and awake at all times.

10.3.6 A counselor shall be available on site to clients at least eight (8) hours a day, seven (7) days a week and available on call twenty-four (24) hours a day.

**10.4 Monitoring and documenting the client's condition**

10.4.1 Upon admission, the program shall record:

10.4.1.1 Client's blood pressure;

10.4.1.2 Client's pulse;

10.4.1.3 Client's respiration;

10.4.1.4 Presence of bruises, lacerations, cuts or wounds;

10.4.1.5 Any medications carried by the client or found on the client's person.

10.4.1.6 Documentation, at a frequency prescribed by Qualified Medical Personnel, but no less than three times in the first eight hours after admission of:

10.4.1.6.1 Blood Pressure;

10.4.1.6.2 Pulse;

10.4.1.6.3 Respiration;

10.4.1.6.4 Type and amount of fluid intake;

10.4.1.6.5 Physical state, including the presence of tremors, ataxia, or excessive perspiration, restlessness, and sleep disturbances;

10.4.1.6.6 Mental state, including the presence of confusion, hallucinations, and orientation to person, place, and time;

10.4.1.6.7 Emotional state, including the presence of anxiety, depression.

**11.0 Standards Applicable to Non-Residential Detoxification**

Services required as determined by the Division of Substance Abuse and Mental Health.

**12.0 Residential Treatment**

**12.1 Services Required**

12.1.1 In addition to the requirements applicable to all programs, a Residential Treatment program shall provide:

12.1.1.1 Medical assessment by qualified medical personnel on the day of admission.

12.1.1.2 A physical examination within seventy-two (72) hours of admission, unless the client presents a copy of a physical examination completed by qualified medical personnel within ninety (90) days prior to admission.

12.1.1.3 A TB test and urine drug screen within seventy-two (72) hours of admission or documentation of a TB test performed within one (1) year prior to admission.

12.1.1.4 An initial treatment plan within forty-eight (48) hours of admission.

- 12.1.1.5 Assessment in accordance with 8.1.2.1.2.14 within forty-eight (48) hours of admission.
- 12.1.1.6 The treatment planning required by 8.1.2.2 within seventy-two (72) hours of admission.
- 12.1.1.7 Treatment plan review/revision and update in accordance with 8.1.2.3 on the fourteenth (14) day after the effective date of the first treatment plan.
- 12.1.1.8 Treatment plan review/revision and update in accordance with 8.1.2.3 on the thirtieth (30) day and every thirty (30) days thereafter.
- 12.1.1.9 A schedule for individual counseling in accordance with the clients individual needs that is reviewed and updated at the time of the treatment plan review.
- 12.1.1.10 A schedule for group and family counseling in accordance with the clients individual needs that is reviewed and updated at the time of the treatment plan review.
- 12.2 Hours of Operation, Staffing and Staff Schedules
  - 12.2.1 Residential programs shall operate twenty-four (24) hours per day, seven (7) days per week.
  - 12.2.2 There shall be staff on duty and awake at all times.
  - 12.2.3 A counselor shall be on site at least eight (8) hours a day, seven (7) days a week and available on call twenty-four (24) hours a day.
  - 12.2.4 Counselors I's and Counselor II's shall meet face-to-face with clinical supervisors a minimum of one (1) hour per counselor per week for clinical supervision.
- 12.3 Nutritional Services
  - 12.3.1 Programs shall establish a written plan for meeting the basic nutritional needs, as well as any special dietetic needs, of clients. Plans shall:
    - 12.3.1.1 include a varied and nutritious diet of at least three (3) meals a day, seven (7) days per week;
    - 12.3.1.2 include snacks as part of the overall dietary plan;
    - 12.3.1.3 include food substitutions, (as applicable);
    - 12.3.1.4 be reviewed by a registered dietitian annually and when they are changed.
- 12.4 Facility Standards
  - 12.4.1 All residential programs shall provide:
    - 12.4.1.1 Separation of sleeping quarters serving male and female clients;
    - 12.4.1.2 Separation of bathroom facilities serving male and female clients;
    - 12.4.1.3 Privacy for personal hygiene;
    - 12.4.1.4 Secure closet and storage space for clients' personal property;
    - 12.4.1.5 Security for valuables, including an inventory and receipt system;
    - 12.4.1.6 Laundry facilities for clients; and
    - 12.4.1.7 Space for solitude.
  - 12.4.2 All agencies operating residential programs shall ensure that in addition to the clients' rights enumerated in 7.0, these additional clients' rights are fully protected:
    - 12.4.2.1 The right to visitation with family and friends, subject to written visiting rules and hours established by the program, except as provided in this subsection.
    - 12.4.2.2 The right to conduct private telephone conversations, subject to written rules and hours established by the program, except as provided in this subsection.
      - 12.4.2.2.1 The Administrator or designee may impose limitations on any of the, visitation and/or phone call procedures when in the judgment of the Administrator, such limitations are therapeutically necessary. Limitations shall be recorded in the client's record.
  - 12.4.3 The right to send and receive uncensored and unopened mail. Program may require the client to open mail or package(s) in the presence of program staff for inspection.
  - 12.4.4 The right to wear his/her own clothing subject to written program rules.

- 12.4.5 The right to bring personal belongings, subject to limitation or supervision by the program.
- 12.4.6 The right to communicate with their personal physician.
- 12.4.7 The right to practice their personal religion or attend religious services, within the program's policies and written policies for attendance at outside religious services.

### **13.0 Transitional residential treatment**

#### **13.1 Services Required**

- 13.1.1 In addition to the requirements applicable to all programs, a Transitional residential treatment program shall provide:

- 13.1.1.1 Meals in accordance with 12.3.
- 13.1.1.2 Housing in accordance with 12.4.
- 13.1.1.3 Physical Examination by qualified medical personnel within seventy-two (72) hours of admission unless the client has had a physical examination completed by qualified medical personnel within ninety-days (90) prior to admission.
- 13.1.1.4 Within seven (7) days of admission, Assessment in accordance with 8.1.2.1.2.14.
- 13.1.1.5 Within seven (7) days of admission, Treatment planning in accordance with 8.1.2.2.
- 13.1.1.6 Treatment plan review/revision in accordance with 8.1.2.3 every thirty (30) days.
- 13.1.1.7 A schedule for individual counseling in accordance with the clients individual needs that is reviewed and updated at the time of the treatment plan review.
- 13.1.1.8 A schedule for group and family counseling in accordance with the clients individual needs that is reviewed and updated at the time of the treatment plan review.
- 13.1.1.9 Medical evaluation and consultation by a licensed physician, as needed.
- 13.1.1.10 Emergency medical and hospital services at a licensed hospital, as needed.

#### **13.1.2 Operation, Staffing and Staff Schedules**

- 13.1.2.1 The program shall operate twenty-four (24) hours per day, seven (7) days per week.
- 13.1.2.2 The program shall have written affiliation agreements for the provision of services required by, when these services are not provided in house.
- 13.1.2.3 When clients are present, there shall be staff on site and on duty at all times.
- 13.1.2.4 A counselor shall be available to clients twenty-four (24) hours a day, seven (7) days per week.

### **14.0 Opioid Treatment Services:**

In addition to these standards, all programs providing Opioid treatment services shall be in full compliance with Federal Regulations regarding Opioid treatment.

#### **14.1 Services Required**

- 14.1.1 A program offering Opioid treatment (OTP) services may provide its clients with a variety of treatment services. It shall provide the services required of residential programs in 12.0 and/or the services required of outpatient programs in 15.0 in addition to the following services:

- 14.1.1.1 An initial screening, documentation of which shall include:

- 14.1.1.1.1 Verification of an applicant's identity, including:

- 14.1.1.1.1.1 name;
- 14.1.1.1.1.2 address;
- 14.1.1.1.1.3 date of birth;
- 14.1.1.1.1.4 government issued photographic identification.

- 14.1.1.1.2 Determination of current physiologic dependence and/or history of dependence upon opium, morphine, heroin or any derivative or synthetic drug



of that group, in accordance with DSM criteria, by medical examination performed by qualified medical personnel. Documentation to support that determination shall include:

- 14.1.1.1.3 Program physician statement that treatment is medically necessary;
- 14.1.1.1.4 The five-axis DSM diagnosis (most current DSM edition.);
- 14.1.1.1.5 A description of behavior(s) supportive of a diagnosis of dependence;
- 14.1.1.1.6 Determination by qualified medical personnel that the person became addicted at least one (1) year before admission to treatment;
- 14.1.1.1.7 Completion of a urine drug screen provided that when Opioid dependence is verified through other indicators, a negative urinalysis shall not preclude admission to the program; and
- 14.1.1.1.8 Determination of the duration of substance dependence.
- 14.1.1.1.9 A physical examination by qualified medical personnel that shall:
  - 14.1.1.1.9.1 Include documentation of the client's general appearance with a focus on the clinical signs and symptoms of addiction;
  - 14.1.1.1.9.2 Document vital signs;
  - 14.1.1.1.9.3 Include a complete medical history;
  - 14.1.1.1.9.4 Include the client's family medical history;
  - 14.1.1.1.9.5 Include medications currently being taken;
  - 14.1.1.1.9.6 Be completed prior to admission; and
  - 14.1.1.1.9.7 Be tetanus immunization review;
- 14.1.1.1.10 Laboratory tests including serology and other tests deemed necessary by the program physician within 14 days of admission:
  - 14.1.1.1.10.1 complete blood count and differential;
  - 14.1.1.1.10.2 investigation of the organ systems for infectious diseases including:
    - 14.1.1.1.10.2.1 documentation of administration and results of intracutaneous PPD within the twelve (12) months prior to admission;
    - 14.1.1.1.10.2.2 documentation of the results of the intracutaneous PPD within the twelve (12) months prior to admission;
    - 14.1.1.1.10.2.3 chest x-ray if intracutaneous PPD results are positive;
    - 14.1.1.1.10.2.4 HIV testing should be encouraged, with the client's signed consent];
    - 14.1.1.1.10.2.5 a biological test for pregnancy for all women of child-bearing age;
    - 14.1.1.1.10.2.6 tetanus immunization review;
    - 14.1.1.1.10.2.7 documentation of administration and results of intracutaneous PPD within the twelve (12) months prior to admission;
    - 14.1.1.1.10.2.8 documentation of the results of the intracutaneous PPD within the twelve (12) months prior to admission;
    - 14.1.1.1.10.2.9 chest x-ray if intracutaneous PPD results are positive;
    - 14.1.1.1.10.2.10 HIV testing should be encouraged, with the client's signed consent;
    - 14.1.1.1.10.2.11 a biological test for pregnancy for all women of child-bearing age;
    - 14.1.1.1.10.2.12 tetanus immunization review;
  - 14.1.1.1.10.3 Completed within fourteen (14) days of admission;
  - 14.1.1.1.10.4 Completed annually thereafter.
- 14.1.1.2 An assessment of each client every ninety (90) days conducted by the program physician. The physician's documentation of this assessment shall include:
  - 14.1.1.2.1 An evaluation of the client's progress in treatment:

- 14.1.1.2.2 The appropriateness of the client's treatment plan, as indicated by the physician's dated signature;
- 14.1.1.2.3 Review current medication(s) and dosage(s) to include:
  - 14.1.1.2.3.1 review of appropriateness of and need for continued use of each medication;
  - 14.1.1.2.3.2 presence of side effects, unusual effects, or contra-indications;
  - 14.1.1.2.3.3 use of multiple medications and drug interactions;
  - 14.1.1.2.3.4 determination of the client's need to be seen face to face by the physician;
  - 14.1.1.2.3.5 Re-writing all orders for the client's medication(s) and dosage(s).
  - 14.1.1.2.3.6 Individual, group and family counseling appropriate to the client's needs.
- 14.2 Special admission populations (where the absence of physiological dependence shall not be an exclusion criterion with a clinically justifiable admission) shall include:
  - 14.2.1 Persons recently released from a penal institution; (within six (6) months after release.)
  - 14.2.2 Pregnant clients; (Program physician shall certify pregnancy)
  - 14.2.3 Previously treated clients; (Up to two (2) years after discharge)
  - 14.2.4 Adolescents, provided that:
    - 14.2.4.1 Individuals under the age of 18 have had two documented attempts at short-term medically supervised withdrawal (detoxification) or drug-free treatment to be eligible for maintenance treatment;
    - 14.2.4.2 in addition to the consent of the client, Individuals under 18 years old, unless otherwise permitted by 16 **Del.C.** §2210 to consent to treatment, have had a parent or legal guardian complete and sign the agency's consent to Methadone Treatment.
- 14.3 Admission procedures in addition to the admission procedures described in 8.1.2.
  - 14.3.1 If an applicant for Opioid treatment services has been discharged within seven (7) years from treatment at another OTP, the admitting program shall document that a good faith effort was made to review whether or not the client is enrolled in any other OTP.
  - 14.3.2 A client enrolled in another program shall not be permitted to enroll in treatment in any other OTP except in exceptional circumstances as determined by the medical director. Exceptions shall be:
    - 14.3.2.1 Noted in the client's record.
- 14.4 Client Orientation
  - 14.4.1 In addition to the requirements of 8.1.2.1.2.11 OTPs shall inform clients of:
    - 14.4.1.1 The facts concerning the use of Methadone, Buprenorphen, Levo-alpha-acetyl-methadol (LAAM) or other Opioid treatment medications dispensed by the program, including, but not limited to:
      - 14.4.1.1.1 an explanation of the interaction between the Opioid treatment medication(s) dispensed by the program and other medications, medical procedures and food;
      - 14.4.1.1.2 any potential adverse reactions, including those resulting from interactions with other prescribed or over-the-counter pharmacological agents, other medical procedures and food; and
      - 14.4.1.1.3 the importance of notifying the client's primary care physician of their admission to and discharge from the program;
    - 14.4.1.1.4 The facts concerning the withdrawal from the use of Methadone, Buprenorphen, LAAM, or other Opioid treatment medications dispensed by the program, including, but not limited to:
      - 14.4.1.1.4.1 policies and procedures regarding voluntary, involuntary, and against medical advise withdrawal from Opioid treatment medications;

- 14.4.1.1.4.2 an explanation of the potential interaction between withdrawal from the Opioid treatment medication(s) dispensed by the program and other medications, medical procedures and food;
      - 14.4.1.1.4.3 any potential adverse reactions as a result of withdrawal from Opioid treatment medications, including those resulting from interactions with other prescribed or over-the-counter pharmacological agents, other medical procedures and food; and
      - 14.4.1.1.4.4 the importance of notifying the client's primary care physician of withdrawal from the program.
- 14.4.2 The program's drug-screening procedure;
- 14.4.3 The program's Opioid treatment medication dispensing procedure, including the days and hours of operation;
- 14.4.4 The program's rules including non-compliance, and discharge procedures, to include administrative Opioid treatment medication withdrawal;
- 14.4.5 The signs and symptoms of overdose and when to seek emergency assistance;
- 14.4.6 The emergency procedures maintained by the program as required in 5.1.4.4.1.21 shall be available twenty-four (24) hours per day.
- 14.4.7 Safe storage practices for take-home Opioid treatment medications;
- 14.4.8 The financial aspects of treatment, including the consequences of nonpayment of required fees.
- 14.4.9 Upon admission, the program shall issue each client a photo identification card.
- 14.5 Client Re-admissions
  - 14.5.1 A client re-admitted to the same program within thirty (30) days need not receive a medical examination and laboratory tests if s/he received a medical examination and laboratory tests within the previous year.
  - 14.5.2 All other requirements of this section, governing the screening and admission of applicants for Opioid treatment, shall apply to individuals seeking readmission to Opioid treatment.
- 14.6 Client Transfers
  - 14.6.1 A client transferring to a different program, need not receive a repeat medical examination and laboratory tests if:
    - 14.6.1.1 all of the information in 14.3.1 has been completed within the past year, and
    - 14.6.1.2 all of the information in 14.3.1 is provided to the receiving program, by the transferring program, prior to admission of the client.
  - 14.6.2 The receiving program physician shall have a transfer summary directly from the transferring program that includes:
    - 14.6.2.1 a medical summary that indicates any significant medical problems;
    - 14.6.2.2 current dosage;
    - 14.6.2.3 dosage regimen for the past twelve (12) months.
  - 14.6.3 All other requirements of 14.0 governing the screening, admission, annual physical examination, and annual laboratory tests required of applicants for Opioid treatment, shall apply to individuals transferring to a OTP, effective as of the date of admission.
  - 14.6.4 The receiving program shall document disclosure of its prescriptive practices and dosing policy to the transferring program at the initial contact regarding transfer of a client.
- 14.7 Non-admissions
  - 14.7.1 Programs shall maintain documentation identifying the following:
    - 14.7.1.1 Each person who was screened or assessed for admission but not admitted;
    - 14.7.1.2 The reason(s) for each non-admission;
    - 14.7.1.3 The specific referrals the program made for each person who was screened or assessed for admission but not admitted.

- 14.7.2 The reasons for non admission must be made available in writing to the client upon request.
  - 14.7.2.1 Documentation of the written response to the non admitted client must be entered into the client file.
- 14.8 Programs that plan to relocate shall:
  - 14.8.1 Inform clients of the date of the move;
  - 14.8.2 Inform clients of the new program location; and
  - 14.8.3 Facilitate transfers of those clients for whom the new program location is not convenient.
- 14.9 Hours of Operation, Staffing, and Staff Orientation
  - 14.9.1 OTPs shall operate six (6) days per week, with at least two (2) hours of medicating time accessible daily outside the hours of 8 a.m. to 5 p.m. Monday through Friday, and three (3) hours on Saturday or Sunday.
  - 14.9.2 Each OTP shall post medication dispensing and counseling hours in a public place within the facility.
  - 14.9.3 Each OTP shall have the services of licensed medical personnel. Staff shall include:
    - 14.9.3.1 A designated medical director, who is a physician, responsible for the administration of all medical services performed by the program and for compliance with all federal, state and local laws, rules and regulations regarding medical treatment of narcotic dependence;
    - 14.9.3.2 At all times when the clinic is open, if a physician is not on site, a physician shall be available for consultations and emergency attendance;
    - 14.9.3.3 Prior to services delivery, in addition to training requirements in 5.1.7.1, OTPs shall provide new staff orientation, including:
      - 14.9.3.3.1 clinical and pharmacotherapy issues,
      - 14.9.3.3.2 overdose, and other emergency procedures,
      - 14.9.3.3.3 provision of services to special populations such as adolescents, pregnant women, and senior citizens.
- 14.10 Minimum urine drug screen testing Drug Abuse Testing
  - 14.10.1 In addition to the initial urine drug screening required in 14.1.1.1.7 the program shall adhere to the following schedule:
    - 14.10.1.1 Three (3) random screens on each client during the first ninety (90) days;
    - 14.10.1.2 Nine (9) additional random screens during the next nine months;
    - 14.10.1.3 Eight (8) random screens on each client in maintenance treatment for each subsequent year; and
    - 14.10.1.4 Monthly random screens on each client receiving a six (6) day supply of take home Opioid treatment medication.
  - 14.10.2 The program shall place any client who has a positive urine drug screen back on the urine drug screen schedule set forth in 14.10 beginning with 14.10.1.1.
  - 14.10.3 Clients' urine samples shall be tested for any other drugs or alcohol, as indicated by the client's use patterns, or that are heavily used in the locale.
  - 14.10.4 Programs shall utilize only laboratories licensed by Federal and State regulatory authorities.
  - 14.10.5 Urine testing Drug abuse testing shall be used as a clinical tool for the purposes of diagnosis and in the development of treatment plans.
  - 14.10.6 Urine drug screen Drug abuse test results shall not be used as the sole criterion to involuntarily discharge any client.
  - 14.10.7 Programs shall place clients transferring from other OTPs on urine surveillance schedule in accordance with subsection 14.10.1.
- 14.11 Administration of Opioid treatment medication

- 14.11.1 No dose of Opioid treatment medication shall be administered until the client has been identified and the dosage compared with the currently ordered and documented dosage level.
- 14.11.2 Only a licensed professional authorized by law may administer or dispense Opioid treatment medication.
- 14.11.3 Ingestion shall be observed and verified by the personnel authorized to administer the Opioid treatment medication.
- 14.11.4 There shall be only one client in the dispensing area at a time.
- 14.11.5 A physician shall obtain a detailed history of drug use within the last twenty-four (24) hours prior to initial dose, and,
  - 14.11.5.1 Determine the client's initial dosage after a physical examination;
  - 14.11.5.2 The initial dose of Methadone shall not exceed thirty (30) mg.;
  - 14.11.5.3 Additional medication shall not be administered, unless:
    - 14.11.5.3.1 after three (3) hours of observation, the physician documents in the client's record that the initial dose did not suppress opiate abstinence symptoms; and
    - 14.11.5.3.2 the physician writes orders for additional medication.
  - 14.11.5.4 The initial total daily dose of Methadone for the first day shall not exceed forty (40) mg., unless the physician documents justification for a higher dosage in the client record that forty (40) mg did not suppress opiate abstinence symptoms.
  - 14.11.5.5 The initial dose of any other Opioid treatment medications shall not exceed federal regulations, guidelines or medical protocol.
  - 14.11.5.6 The program physician shall justify any deviations from dosages, frequencies, and conditions of usage described in the approved product labeling.
- 14.11.6 A physician shall determine all subsequent dosage levels and shall:
  - 14.11.6.1 Document each order change on the physician's medication orders;
  - 14.11.6.2 Sign each order change; and
  - 14.11.6.3 Date the order.
- 14.11.7 Programs shall dispense Methadone in an oral form, in accordance with federal and state law and regulations in containers conforming to 42 CFR (Part VIII) Section 12.(i)(5).
- 14.11.8 Any Opioid treatment medication error or adverse drug reaction shall be reported promptly to the medical director and an entry made in the client's record.
- 14.11.9 The medical director shall ensure that significant adverse drug reactions are reported to the Federal Food and Drug Administration and to the manufacturer in a manner that does not violate the client's confidentiality.
- 14.11.10 Each program shall develop a written emergency procedure to be implemented in the case of an employee strike, fire or other emergency situation that would stop or substantially interfere with normal dispensing operations. The emergency procedure shall comply with 9.3 and also include:
  - 14.11.10.1 Arrangements with a security provider for immediate security of Opioid treatment medications;
  - 14.11.10.2 Written agreements, updated annually, with back-up licensed professionals authorized by law, for the coverage of dispensing and other medical needs if regular personnel are not available;
  - 14.11.10.3 A reliable system for confirming the identities of clients before dispensing; and
  - 14.11.10.4 Written agreements, updated annually, for the use of an alternate program, hospital or other site for dispensing during an emergency period.
- 14.12 Opioid treatment medication schedules; Unsupervised or "take-home use":
  - 14.12.1 Treatment program decisions on dispensing unsupervised or "take-home" medications shall be determined by the medical director. The medical director shall consider the following criteria to determine whether a patient is responsible in handling drugs for unsupervised use.

- 14.12.1.1 Regularity of program attendance;
- 14.12.1.2 Absence of recent abuse of drugs, including alcohol;
- 14.12.1.3 Regularity of clinic attendance;
- 14.12.1.4 Absence of serious behavioral problems at the clinic.
- 14.12.1.5 Absence of known recent criminal activity (e.g. drug and drug related arrests, etc.
- 14.12.1.6 Progress in meeting treatment plan goals;
- 14.12.1.7 Length of time in treatment;
- 14.12.1.8 Responsibility in the handling, and plan for the safe storage, of take home Opioid treatment medications;
- 14.12.1.9 Stability of the client's home environment and social relationships.
- 14.12.1.10 When it is determined that a patient is responsible in handling Opioid drugs, the Federal Regulations for take home privileges shall be applied.
- 14.12.2 OTPs shall maintain current procedures adequate to identify the theft or diversion of take-home medications, including:
  - 14.12.2.1 labeling containers with the OTP's name, address, and telephone number; and
  - 14.12.2.2 requiring patients to come to the clinic on a randomly scheduled basis for drug testing and checking the amount of take-home medication used to that point.
- 14.12.3 Programs shall also ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers.
- 14.13 Revocation of take-home privileges.
  - 14.13.1 The program medical director will determine if a client's conduct warrants revocation or suspension of take-home privileges.
    - 14.13.1.1 Documentation of the rationale for revoking or suspending take-home privileges will be entered into the client's record by the medical director.
- 14.14 Exceptions.
  - 14.14.1 If, in the judgment of the program physician:
    - 14.14.1.1 a client has a physical disability that interferes with his or her ability to conform to the applicable mandatory attendance schedule, the program physician may permit a reduced attendance schedule, provided that the physician comply with 14.12.1 and documents reasons for permitting take home medication.
    - 14.14.1.2 a client is unable to conform to the applicable mandatory attendance schedule because of exceptional circumstances such as illness, personal or family crises, travel, or other hardship, the program physician may permit a temporarily reduced schedule, provided that the client is responsible in handling Opioid treatment medications. In such cases, the program physician shall record or verify the rationale for the exception in the client's record and date and sign the record.
  - 14.14.2 Employed clients may apply for an exception to these requirements if the dispensing hours of the clinic conflict with working hours of the client. In such cases, the client may receive take-home medications after verifying work hours through reliable means, provided that the physician complies with 14.12.1 and documents reasons for permitting take home medication.
  - 14.14.3 Any client who transfers from one (1) OTP to another shall be eligible for placement on the same take-home schedule. Before initiating take-home privileges for a client transferring from other maintenance treatment programs, the program physician shall comply with subsection 14.12.1 and documents reasons for permitting take home medication.
- 14.15 Voluntary Medical withdrawal from Opioid treatment Medication
  - 14.15.1 Voluntary medical withdraw from Opioid treatment medication shall include:
    - 14.15.1.1 A request signed and dated by the client, for voluntary medication withdrawal.
    - 14.15.1.2 Documentation of the physician's rationale for initiation of withdrawal.
    - 14.15.1.3 Documentation of the physician's rationale for continuing the withdrawal if there is any change in the physician's orders.

- 14.15.1.4 Documentation signed and dated by the client, that the withdrawal will be discontinued and maintenance resumed at the client's request.
- 14.15.1.5 A biological test for pregnancy for all women of child-bearing age prior to the initiation of withdrawal.
- 14.15.1.6 Revision of the treatment plan with an increase in counseling and other support services in relation to medication dosage changes.
- 14.15.1.7 Provisions for continuing care after the last dose of Opioid treatment medication.
- 14.16 Withdraw against medical advice
  - 14.16.1 Withdrawal against medical advice shall include:
    - 14.6.1.1 Documentation of all efforts taken by staff members to discourage initiation and continuation of withdrawal against medical advice.
    - 14.6.1.2 Documentation of the reasons the client is seeking withdrawal against medical advice.
- 14.17 Involuntary withdrawal:
  - 14.17.1 Involuntary withdrawal from an Opioid treatment medication shall be conducted in accordance with a dosage reduction schedule prescribed by the physician.
  - 14.17.2 Clients being involuntarily discharged shall be referred to other treatment, as clinically indicated.
  - 14.17.3 OTPs shall document the reasons for initiation of involuntarily withdrawal in the client's record.
  - 14.17.4 Prior to the beginning of involuntary withdrawal, efforts should be documented regarding referral or transfer of the client to a suitable, alternative treatment program.
  - 14.17.5 Involuntary withdrawal shall be considered a planned discharge and shall comply with 8.1.2.7 regarding the planned discharge of a client.
  - 14.17.6 Documentation during withdrawal shall include:
    - 14.17.6.1 Documentation by the physician of the schedule for withdrawal and any changes made to the schedule by the physician during the withdrawal.
    - 14.17.6.2 Counseling designed to promote the continuation of services following medical withdrawal.
- 14.18 Detoxification treatment
  - 14.18.1 An OTP shall maintain procedures that are designed to ensure that qualified medical personnel admit clients to short- or long-term detoxification treatment.
  - 14.18.2 Patients with two or more unsuccessful detoxification episodes within a twelve (12) month period shall be assessed by the OTP physician for other forms of treatment.
  - 14.18.3 A program shall not admit a client for more than two (2) detoxification treatment episodes in one year.
- 14.19 Pregnant Clients
  - 14.19.1 In addition to the other requirements of this section, for pregnant clients the following shall apply:
    - 14.19.1.1 OTPs shall provide priority in initiating treatment.
    - 14.19.1.2 The physician shall document in the client record all clinical findings supporting the certification of the pregnancy prior to the administration of an initial dose of Opioid treatment medication.
    - 14.19.1.3 The initial dose of Methadone shall not exceed 40 mg.
    - 14.19.1.4 The program physician shall evaluate dosing of pregnant women weekly during the last trimester of the pregnancy.
    - 14.19.1.5 If there is simultaneous use of alcohol and/or other drugs the program shall document:
      - 14.19.1.5.1 Education of the client regarding the potential impact of substance use on the fetus.

- 14.19.1.5.2 Attempts to encourage the client to cease use of substances other than those prescribed by a physician.
- 14.19.1.5.3 Referrals made to appropriate levels of care.
- 14.19.1.6 Pregnant clients shall be given the opportunity for prenatal care either by the program or by referral to appropriate health care providers.
- 14.19.1.7 The program shall document all attempts to assist the client with obtaining prenatal care.
- 14.19.1.8 The program shall offer prenatal instruction on:
  - 14.19.1.8.1 Education on fetal development;
  - 14.19.1.8.2 Care for the newborn;
  - 14.19.1.8.3 Breastfeeding;
  - 14.19.1.8.4 Effects of maternal drug use on the fetus;
  - 14.19.1.8.5 Information on parenting;
  - 14.19.1.8.6 Importance of sound maternal nutritional practices.
- 14.19.2 OTP's shall give priority to pregnant women seeking admission to treatment.
- 14.19.3 OTP's shall maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal and other gender specific services shall be provided either by the OTP or by referral to appropriate health care providers.
- 14.19.4 Medical withdrawal of the pregnant, Opioid – addicted woman from Opioid treatment medication is not indicated or recommended. No pregnant client shall be involuntarily medically withdrawn from an Opioid treatment medication.
- 14.19.5 Pregnant individuals who choose to withdraw from treatment against medical advice shall do so under the direct supervision of the program physician in conjunction with an obstetrician who can monitor the effects on the fetus.
- 14.19.6 If a pregnant client refuses direct treatment, referral for treatment, or referral for other services, the program physician shall have the client acknowledge said refusal in writing. Documentation of the refusal shall be recorded in the client's record.
- 14.19.7 The program physician shall request the physician, hospital, or program to which the individual is referred, to provide reports of prenatal care, and a summary of the delivery and treatment outcome for the client and baby. Documentation of the request(s) shall be included in the client's record.
- 14.19.8 Within three (3) months after termination of the pregnancy, the program physician shall evaluate the individual's treatment status and document whether she should remain in the comprehensive maintenance program or be detoxified.
- 14.20 Programs shall be accredited by an accreditation body approved by SAMSHA and registered with the DEA, as required.

## **15.0 Outpatient Treatment**

### **15.1 Services Required**

- 15.1.1 In addition to the requirements applicable to all programs, an Outpatient Treatment program shall provide:
  - 15.1.1.1 Documentation of a physical examination by qualified medical personnel within ninety (90) days prior to admission.
    - 15.1.1.1.1 When documentation of a physical examination by qualified medical staff is not made available to the program, the program shall document a good faith effort in referring the client for a physical and/or efforts made to obtain documentation of a physical.
  - 15.1.1.2 Assessment in accordance with 8.1.2.1.2.14 within thirty (30) days of admission.
  - 15.1.1.3 Treatment planning in accordance with 8.1.2.2 within thirty (30) days of admission or by the fourth (4<sup>th</sup>) counseling session, whichever occurs first.



- 15.1.1.4 Treatment plan review/revision in accordance with 8.1.2.3 every ninety (90) days after the effective date of the first treatment plan.
- 15.1.1.5 A schedule for individual, group and family counseling in accordance with the clients individual needs that is reviewed and updated at the time of the treatment plan review.
- 15.2 Any time that services are offered at locations other than the program's main building, the program will assure that all requirements of 9.0 of these regulations are met in full.

**Part IV-- Provisions Regarding Deemed Status**

**16.0 Commission on Accreditation of Rehabilitation Facilities (CARF)**

- 16.1 Deemed Status Categories
  - 16.1.1 Programs with Three-Year Accreditation will qualify for a two (2) year license.
  - 16.1.2 Programs with One-Year Accreditation will qualify for a one (1) year license or less (at the discretion of the Division Director).
  - 16.1.3 Programs with Provisional Accreditation will qualify for Deemed Status at the discretion of the Division Director.
  - 16.1.4 Programs with Provisional Accreditation must submit all corrective action reports prepared for CARF to DSAMH at the same time they are submitted to CARF.
  - 16.1.5 Programs with Provisional Accreditation must submit copies of progress reports prepared for CARF to DSAMH at the time they are sent to CARF until the program is granted a Three-Year or One-Year Accreditation. Deemed Status will be re-evaluated annually when the program holds Provisional Accreditation status and is not guaranteed year to year.
  - 16.1.6 Programs that are accredited as part of a merger, consolidation or acquisition must submit verification that CARF will extend accreditation to the new entity.
- 16.2 Notification of Audit:
  - 16.2.1 Programs must inform DSAMH of all CARF visits whether announced or unannounced. The DSAMH Licensing Unit should be notified in writing of a scheduled visit no less than 30 days prior to the visit. The Licensing and Medicaid Certification Unit should be notified by phone or email of an unannounced visit within 24 hours of the first day of the visit.
- 16.3 Reporting to DSAMH
  - 16.3.1 Programs must notify DSAMH of any immediate threat to life that is discovered by CARF during the visit within 24 hours of the day the threat to life is discovered.
  - 16.3.2 Programs must report all other *significant events* to DSAMH within 24 hours accompanied by the investigation report; action plan and action plan follow up activity reports prepared according to CARF guidelines.
  - 16.3.3 Programs must submit to DSAMH any corrective action to address significant events at the same time they are submitted to CARF.
  - 16.3.4 Programs must submit to DSAMH any other correspondence required by CARF during the course of the Accreditation period and/or between each CARF review.
- 16.4 Deemed Status Revocation
  - 16.4.1 DSMAH can revoke Deemed Status standing at any time, but specifically when:
    - 16.4.1.1 A program is unsuccessful in receiving Three-Year, One-Year, or Provisional Accreditation from CARF;
    - 16.4.1.2 In response to a significant event;
    - 16.4.1.3 When reporting to DSAMH does not occur in accordance with the time table established above;
    - 16.4.1.4 Following a survey by DSMAH when it is determined that the program is not operating under the CARF guidelines and/or DSAMH licensure standards.

16.4.2 Once revoked, a program must wait one (1) year before reapplying for Deemed Status. DSAMH must conduct a site review before restoring Deemed Status.

16.5 Program Exemptions:

16.5.1 Programs are exempt from the Division of Substance Abuse and Mental Health standards for Substance Abuse Treatment Programs with the exception of:

16.5.1.1 ***Standards Applicable to all Programs:***

16.5.1.1.1 Section 5.0: Programs with Deemed status must be in compliance with the following subsections of section 5.0:

16.5.1.1.1.1 Subsection 5.1.3.1;

16.5.1.1.1.2 Subsections 5.1.6.3.5.3., 5.1.6.3.5.5., 5.1.6.3.5.6., 5.1.6.3.5.7., 5.1.6.3.5.8., 5.1.6.3.5.9;

16.5.1.1.1.3 Subsection 5.1.6.4;

16.5.1.1.1.4 Subsection 5.1.6.5;

16.5.1.1.1.5 Subsection 5.1.7.4.

16.5.1.1.2 Section 6.0: Programs must be in compliance with all of section 6.0.

16.5.1.1.3 Section 8.0: Programs with Deemed Status are exempt from sub-section 8.1.2 of section 8.0. When client records are reviewed, DSAMH will accept documents in section 8.1.2 in the format accepted by CARF. Programs must be in compliance with all other subsections of section 8.0.

16.5.1.1.4 Section 9.0: Programs must be in compliance with standard 9.1.5: "smoke free facility".

16.5.1.2 Standards Applicable to Specific Settings and Modalities

16.5.1.2.1 Programs must be in compliance with all standards specific to the modality for which the program is being licensed with the exception of:

16.5.1.2.1.1 Section 14: Opioid Treatment: Opioid Treatment programs with Deemed Status are exempt from all requirements of section 14 with the exception of:

16.5.1.2.1.1.1 Subsection 14.3;

16.5.1.2.1.1.2 Subsection 14.4;

16.5.1.2.1.1.3 Subsection 14.9;

16.5.1.2.1.1.4 Subsection 14.11;

16.5.1.2.1.1.5 Subsections 14.12 through 14.20.

**17.0 Joint Commission on the Accreditation of Healthcare Organizations (JCAHO)**

17.1 Deemed Status Categories:

17.1.1 Programs with Full Accreditation will qualify for a two (2) year license.

17.1.2 Programs with Provisional Accreditation will qualify for a one (1) year license or less (at the discretion of the Division Director).

17.1.3 Programs with Conditional Accreditation will qualify for Deemed Status at the discretion of the Division Director.

17.1.4 Programs with Provisional Accreditation must submit all corrective action reports prepared for JCAHO to DSAMH at the same time they are submitted to JCAHO.

17.1.5 Programs with Conditional Accreditation must submit copies of progress reports prepared for JCAHO to DSAMH at the time they are sent to JCAHO until the program is granted a Three-Year or One-Year Accreditation. Deemed Status will be re-evaluated annually when the program holds Provisional Accreditation status and is not guaranteed year to year.

17.1.6 Programs that are accredited as part of a merger, consolidation or acquisition must submit verification that JCAHO will extend accreditation to the new entity.

17.2 Notification of Audit:

- 17.2.1 Programs must inform DSAMH of all JCAHO visits whether announced or unannounced. The DSAMH Licensing Unit should be notified in writing of a scheduled visit no less than 30 days prior to the visit. The Licensing and Medicaid Certification Unit should be notified by phone or email of an unannounced visit within 24 hours of the first day of the visit.
- 17.3 Reporting to DSAMH
  - 17.3.1 Programs must notify DSAMH of any immediate threat to life that is discovered by JCAHO during the visit within 24 hours of the day that the threat to life is discovered.
  - 17.3.2 Programs must report all *sentinel events* to DSAMH within 24 hours accompanied by the root cause analysis, action plan and action plan follow up activity reports prepared according to JCAHO guidelines.
  - 17.3.3 Programs must submit to DSAMH any corrective action to address *sentinel events* at the same time they are submitted to JCAHO.
  - 17.3.4 Programs must submit to DSAMH any other correspondence required by JCAHO during the course of the Accreditation period and/or between each JCAHO review.
- 17.4 Deemed Status Revocation
  - 17.4.1 DSMAH can revoke Deemed Status standing at any time, but specifically when:
    - 17.4.1.1 A program is unsuccessful in receiving Accreditation, or Provisional Accreditation from JCAHO;
    - 17.4.1.2 In response to a sentinel event;
    - 17.4.1.3 When reporting to DSAMH does not occur in according with the time table established above;
    - 17.4.1.4 Following a survey by DSMAH when it is determined that the program is not operating under the JCAHO guidelines and/or DSAMH licensure standards.
  - 17.4.2 Once revoked, a program must wait 1 year before reapplying for Deemed Status. DSAMH must conduct a site review before restoring Deemed Status.
- 17.5 Program Exemptions:
  - 17.5.1 Programs are exempt from the Division of Substance Abuse and Mental Health standards for Substance Abuse Treatment Programs with the exception of:
    - 17.5.1.1 Standards Applicable to all Programs:
      - 17.5.1.1.1 Section 5.0:
        - 17.5.1.1.1.1 Subsection 5.1.2.1;
        - 17.5.1.1.1.2 Subsection 5.1.4;
        - 17.5.1.1.1.3 Subsection 5.1.7.1;
        - 17.5.1.1.1.4 Subsection 5.1.7.2;
        - 17.5.1.1.1.5 Subsection 5.1.7.3;
        - 17.5.1.1.1.6 Subsection 5.1.8;
      - 17.5.1.2 Section 6.0: Programs must be in compliance with all of section 6.0.
      - 17.5.1.3 Section 8.0: Programs with Deemed Status are exempt from sub-section 8.1.2 of section 8.0. When client records are reviewed, DSAMH will accept documents in section 8.1.2. in the format accepted by JCAHO. Programs must be in compliance with all other subsections of section 8.0.
    - 17.5.2 Section 9.0: Programs with Deemed Status are exempt from all standards in section 9.0. with the exception of 9.1.5. "smoke free facility".
- 17.6 Standards Applicable to Specific Settings and Modalities
  - 17.6.1 Programs must be in compliance with all standards specific to the modality for which the program is being licensed with the exception of:
    - 17.6.1.1 Section 14.0: Opioid Treatment: Opioid Treatment programs with Deemed Status are exempt from all requirements of section 14.0 with the exception of:
      - 17.6.1.1.1 Subsection 14.3;
      - 17.6.1.1.2 Subsection 14.4;
      - 17.6.1.1.3 Subsection 14.9;

17.6.1.1.4 Subsection 14.11;

17.6.1.1.5 Subsections 14.12 through 14.20.

**12 DE Reg. 464 (10/01/08)**